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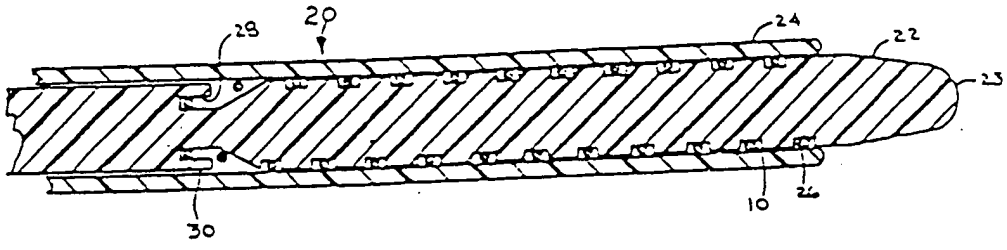
(54) Title: AN INTRAVASCULAR STENT AND PERCUTANEOUS INSERTION SYSTEM



(57) Abstract

A method and apparatus for preventing arterial restenosis by placing a coil spring stent into the vessel. A stent insertion catheter (20) contains an outer cylinder (24) and inner core (22) within a tapered front (23) and spiral grooves (26). The coil stent (10) is placed within the spiral grooves. When the outer cylinder (24) is pulled back the coil stent is deployed. Also disclosed is a novel coil stent having a plurality of layers. The outer layer (46) is made from a non-thrombogenic material.

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An Intravascular Stent and Percutaneous Insertion System

This invention is in the field of percutaneous insertion catheters that are used for placing a coil spring stent into a vessel of a living body for the purposes of enhancing luminal dilation, preventing arterial restenosis and preventing vessel blockage resulting from intimal dissection following balloon and other methods of angioplasty. The stent can also be used for the maintaining patency of many different ducts or vessels within a living body.

BACKGROUND OF THE INVENTION

In the last decade there has been increasing use of percutaneous transluminal balloon angioplasty for the opening of stenosis of the peripheral and coronary arteries. In this procedure the uninflated balloon at the tip of the catheter is advanced into the narrowed portion of the arterial lumen. The balloon is then inflated so as to push the stenotic plaque outward thereby enlarging the luminal diameter and improving distal perfusion. The balloon is then deflated and the catheter is withdrawn from the body. Initially the blood flow at that point is typically improved to a significant degree. However, within six months, restonosis, defined as a loss of more than 50% of the initial enlargement of arterial diameter, occurs in approximately 30% of cases. It would therefore be of great value if a means could be devised to retain patency (i.e., opening) of the artery so that adequate blood flow would be maintained.

The concept of placing a coil spring intravascular stent within an artery is not new. In the September-October 1969 edition of INVESTIGATIVE RADIOLOGY, C. T. Dotter reported the insertion of 6 coil spring intravascular stents in the arteries of dogs. Three of these springs which were covered with silicone rubber occluded within 24 hours. Two out of three, bare stainless steel wire springs remained patent at 2½ years. Dotter also described a "pusher-catheter" of equal diameter with the spring outer diameter which was used to place the springs within the artery.

In more recent work, D. Maas et al in the September 1984 edition of Radiology described improved stainless steel coil spring intravascular stents that were implanted in 65 dogs and 5 calves. a 100% success rate was reported using bare, heat treated steel alloy springs that were torqued to a reduced diameter and inserted with a special device designed for that purpose. Neither Dotter nor Maas et al were able to perform a percutaneous procedure for the stent insertion. Dotter describes a "pusher-catheter" that was of equal diameter to the outside diameter of the coil spring. Maas et al used a 7mm diameter special insertion device that applied torque to the coil spring to reduce its diameter to 7mm; i.e., the deployed outside diameter was greater than 7mm. Since the largest practical outside diameter for percutaneous delivery is less than 4mm, the device and methods used by Maas et al are not practical for percutaneous insertion.

The results of Dotter, i.e., 2 of 3 patent arteries at the end of 2½ years using comparatively small (3.5mm) diameter coil are probably not good

enough for clinical applications. The results of Maas et al were very good, but these were for inside diameters greater than 7mm.

What is really needed and not described by either Dotter or Maas et al or anyone else is a safe and simple method for percutaneous transluminal insertion of a coil spring stent whose insertion device structure allows an insertion catheter of outer diameter less than 4mm. Another requirement of the insertion device is that it maintains the reduced diameter of the coil spring stent during insertion and allows the coil to expand to a diameter greater than the diameter of the arterial lumen after removal of the insertion catheter.

To make the intravascular stent (IS) safe for human use even in small diameter coronary arteries, it is necessary for the spring material to be biocompatible and non-thrombogenic. The greatest success by Dotter and Maas et al was with bare metal coil springs. However, no investigation to date has described use of these stents in either human subjects or in animal coronary arteries. Furthermore, Dotter quotes an article which states that "It appears that success or failure of an arterial substitute in dogs bears no direct relationship to the results one will obtain when a similar substitute is used clinically for the peripheral arteries". Hence one must be concerned with the human biocompatability of the material used for the IS.

Many articles such as "ULTI Carbon Goretex: A New Vascular Graft" by R. Debski et al in the May-June 1983 edition of Current Surgery describe the

superior non-thrombogenic characteristics of ultra low-temperature isotropic (ULTI) carbon as such a blood compatible material. The use of carbon as a blood compatible material for humans is well known among those skilled in the art of vascular grafts and prosthetic heart valves. However, no investigator of IS devices has ever described the use of carbon coated coil springs or carbon coated polytetrafluoroethylene (PTFE) covered coil springs to solve the problem of thrombosis of small diameter IS devices in humans.

It should be noted that nothing in the prior art describes the use of a coil spring stent for the prevention of arterial blockage due to intimal dissection (tearing away of the intima layer) following balloon angioplasty. There is approximately a 30% incidence of radiologically detectable intimal dissection following routine percutaneous transluminal coronary angioplasty (PTCA). In many of these cases this is not a problem. Vessel wall healing and remodeling typically restores a smooth luminal contour with good vessel patency within several weeks following the angioplasty. In a small but significant subset of these patients, the intimal dissection may be severe, resulting in a high risk of vessel closure within 24 hours following PTCA. These patients will typically sustain some degree of myocardial infarction despite further aggressive attempts at revascularization, including coronary artery bypass surgery.

SUMMARY OF THE INVENTION

Thus it is an objective of the present invention to utilize a coil spring intravascular stent (IS) for the prevention of arterial restenosis.

A second objective of the invention is to utilize an IS to further enlarge the luminal diameter after successful percutaneous transluminal angioplasty.

Another objective is to provide a percutaneous transluminal catheter means for placing the IS at the appropriate place within the artery.

Still another objective is to describe a method for percutaneous insertion of intravascular stents.

Still another objective is to provide a means and method for preventing arterial blockage due to intimal dissection following balloon or other types of angioplasty.

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1A, 1B, and 1C are cross-sectional views showing respectively the shape of the plaque within an arterial wall, (A) before balloon dilation, (B) immediately after balloon dilation, and (C) at several months after dilation.

Figs. 2 is a cross-sectional view of an IS in the form of a coil spring placed in a position to prevent restenosis and/or provide additional dilation of the plaque.

Fig. 3 is a cross-sectional view of the distal end of an insertion catheter for inserting the IS.

Fig. 4 is a cross-sectional view of the proximal end of the insertion catheter.

Fig. 5 is a cross-sectional view of a wire coated with ULTI carbon.

Fig. 6 is a cross-sectional view of a wire enclosed by PTFE and coated with ULTI carbon.

DETAILED DESCRIPTION OF THE INVENTION

Figs. 1A, 1B, and 1C are cross-sectional view of an arterial wall AW surrounding a plaque P which forms an arterial stenosis or narrowing. It is well known in the art to utilize percutaneous transluminal balloon angioplasty to dilate the stenosis of Fig. 1A by expanding a balloon that is placed within the narrowed lumen. The result immediately after balloon dilation is shown in Fig. 1B. However, in approximately 30% of all balloon procedures, there is a restenosis of the artery as illustrated in Fig. 1C.

If, however, a coil spring intravascular stent (IS) 10 is placed at the dilation site immediately after balloon dilation in a position as shown in Fig. 2, the resistance of the IS 10 to deformation by inwardly directed radial pressure can preclude restenosis of the artery. Furthermore, if the constrained diameter of that IS 10 as shown in Fig. 2 is less than the free diameter of the coil spring IS 10, then additional dilation may occur following the insertion of the IS 10. Furthermore, if the intima layer was torn(i.e dissected) during balloon dilation, the IS 10 can hold that intima layer in place and prevent subsequent blockage of the artery which can result from the effect of blood flow causing the torn intima to come off the wall of the dilated stenosis.

Fig. 3 shows the distal end of the insertion catheter 20 which consists of an inner core 22 and an outer cylinder 24. The core 22 has a rounded and tapered front end 23 and spiral grooves 26 into which the coil spring IS 10 is placed. The core 22 has a back groove 28 which contains the most proximal coil of the coil spring IS 10 which is prevented from springing radially outward by the flange 30.

Fig. 4 is a cross-sectional view of the proximal end of the insertion catheter 20. A cylindrically shaped cylinder handle 32 is molded onto the outer cylinder 24. A cylindrically shaped cylinder handle 32 is molded onto the outer cylinder 24. Similarly, a cylindrically shaped core handle 36 is molded onto the core 22. A conically shaped interior surface 34 of the cylinder handle 32 is used to help guide the cylinder handle 32 over the IS 10 as it is mounted on the distal end of the insertion catheter 20. The distance D in Fig. 4 is initially set to be slightly greater than the length of the IS 10 at the distal end of the insertion catheter 20.

The spring IS 10 is loaded onto the distal end of the core in the following manner:

1. A pair of pliers is used to hold the most distal portion of the IS 10 into the most distal spiral groove 26 of the inner core 22.

2. The spring IS 10 is then pulled and twisted applying torque to its most proximal end so that the spring IS 10 is forced into the spiral grooves 26.

3. A pliers wide enough to hold all turns of the IS 20 in place except the most proximal turn and the most distan turn is then applied at the center of the IS 10 to hold it in the spiral grooves 26.

4. A needle nose pliers is then used to force the most proximal turn of the IS 10 into the core groove 28.

5. The conical interior surface 34 of the cylindrical handle 32 is then fed over the most distal turn of the IS 10 as it sits in the most distal groove 26 of the core 22.

6. As the handle 32 is moved in the proximal direction, the broad pliers holding the central portion of the IS 10 in place is simultaneously moved in the proximal direction until the entire IS 10 is covered by the interior surface of the handle 32 and the outer cylinder 24.

7. The handle 32 is then pulled in a proximal direction until the distal end of the cylinder 24 lies just over the last turn of the IS 10 which occurs when the cylinder handle 32 and the core handle 36 are separated by a distance D as shown in Fig. 4.

In this manner, a coil spring IS 10 whose unrestrained (i.e., free) diameter can be between 1.1 to 5.0 times larger than its diameter when stored on the core 22 can be placed at the distal end of the insertion catheter 20.

Deployment of the spring IS 10 within a recently dilated occlusion is accomplished in the following steps:

1. By conventional means, a guiding catheter (not shown) is placed percutaneously into the femoral artery and its distal end is advanced to the site where the IS 10 is to be released.

2. Under fluorscopic control, the insertion catheter 20 is advanced through the guiding catheter until the center of the IS 10 is positioned at the center of the recently dilated stenosis.

3. While holding the core handle 36 firmly against the body so that it does not move, the outer cylinder handle 32 is moved proximally so as to decrease to zero the distance D of Fig. 4.

4. All turns of the IS 10 except the most proximal turn are then expanded outward to engage the interior surface of the recently dilated stenosis.

5. The core 22 and the outer cylinder 24 are then pulled out of the body together which leaves the coil spring IS 10 in its desired place in the artery.

An angioplasty balloon could then be expanded within the IS 10 so as to more firmly imbed the spring into the stenotic plaque. The balloon and guiding catheters would of course be removed from the body after they were used for their intended purposes.

The coil spring used in this manner would:

1. Prevent restenosis of the occlusion.

2. Increase the lumen diameter by constantly applying an outward radial force to the plaque, and

3. Hold in place any intima layer torn from the stenosis during balloon dilation which might otherwise tend to block blood flow in that artery.

The materials of the core 22, core handle 36, outer cylinder 24 and outer cylinder handle 32 might be PVC or some other comparatively strong plastic. The IS 10 might be fabricated from a stainless spring steel or an alloy of titanium such as Ti-6Al-4V. The outside diameter of the unrestrained coil spring IS 10 might vary from 2 to 12mm depending on the lumen diateter into which it is implanted. The wire diameter might be between 0.1 and 0.5mm. The outer diameter of the outer cylinder 24 would be less than 4mm. The length of the IS 10 would be between 5 and 25mm depending upon the length of the dilated stenosis into which it would be placed.

Decreased thrombogenicity can be achieved by coating the outside of the coil with a non-thrombogenic material such as ULTI carbon. An enlarged cross section of such a sire is shown in Fig. 4. The metallic core is shown as 40 and the coating is shown as 42. Coating thickness might be as thin as 0.01mm or as thick as o.1mm.

Fig. 5 shows another enlarged cross section of the wire of the IS 10 in which the metallic core 40 is first covered by a plastic layer 44 such as PTFE and then coated with a non-thrombogenic coating 46 such as ULTI carbon. The plastic coating would typically be between 0.05 and 0.5mm and the non-thrombogenic coating might have a thickness between 0.01 and 0.5mm.

Although this intravascular stent might find its greatest application as a means to enhance balloon

angioplasty in humans it could also be used to successfully provide permanent dilation and patency of other ducts and vessels within a living human or animal body. For example, this coil spring intravascular stent 10 could also be used to maintain long term patency of ureters or fallopian tubes. In every use, the fact that wire diameter would be typically 1/10 the coil spring pitch length i.e., only 10% of the lumen interior surface is actually in contact with a foreign material. Therefore, normal body cells could grow over the coils of such springs. Thus, the normal characteristics of the interior lining of such ducts or vessels would be only minimally compromised.

Various other modifications, adaptations, and alternative designs are, of course, possible in light of the above teachings. Therefore, it should be understood at this time that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

What is claimed is:

1. An insertion catheter for inserting a coil spring stent into a vessel or duct of a living body, comprising:

an outer sheathing cylinder having an inner lumen; and,

an inner core means, adapted to cooperate with said inner lumen of said sheathing cylinder, for maintaining the coil stent at a first reduced diameter during insertion within the vessel or duct of a living body, and for allowing the coil stent to expand to a second greater diameter as the distal end of said sheathing cylinder is moved in a proximal direction away from the distal end of said inner core means.

2. The apparatus of claim 1, wherein the outer surface of said inner core means has formed therein a spiral groove, wherein cooperation of said spiral groove with said inner lumen of said sheathing cylinder forms a spiral cavity adapted to contain the coil stent at said first reduced diameter.

3. The apparatus of claim 2, wherein said inner core means further comprises a flange means, adapted to frictionally engage the proximal end of the coil stent.

4. The apparatus of claim 3, wherein said flange means comprises:

a back groove cut into the surface of said inner core means and adapted to contain the proximal end of the coil stent; and,

a flange located adjacent to said back groove and adapted to prevent radial movement of the coil stent which is frictionally engaged.

5. The apparatus of claim 1, wherein said inner core means comprises a rounded and tapered distal end.

6. The apparatus of claim 1, further comprising a control means for moving the distal end of said sheathing cylinder relative to the distal end of said inner core means.

7. The apparatus of claim 6, wherein the proximal ends of said sheathing cylinder and said inner core means extend external to said living body, and wherein said control means comprises a first handle operably coupled to a proximal portion of said sheathing cylinder, and a second handle operably coupled to a proximal portion of said inner core means, wherein movement of said first handle toward said second handle causes movement of the distal ends of said sheathing cylinder and inner core means so as to release said coil stent.

8. An insertion catheter, comprising:
an outer sheathing cylinder having an inner lumen; and,

an inner core member adapted to fit within the inner lumen of said sheathing cylinder, the outer surface of said inner core member having formed therein a spiral groove, wherein cooperation of said spiral groove, wherein cooperation of said spiral groove with said inner lumen of said sheathing cylinder forms a spiral cavity adapted to contain a coil spring stent.

9. The apparatus of claim 8, wherein said inner core member further comprises a second groove formed along the circumference of the outer surface of said inner core member at a location proximally to said spiral groove, and a longitudinal flange extending along the outer surface of said inner core member into said second groove, thereby forming a second channel, said second channel adapted to frictionally engage the proximal end of a coil spring stent.

10. The apparatus of claim 8, further comprising a control means operably coupled to said sheathing cylinder and said inner core member, for moving the distal end of said sheathing cylinder a linear distance relative to the distal end of said inner core means.

11. A stent formed from a coil spring wire, said wire comprising:
an inner metallic core; and
a layer of non-thrombogenic material coating the inner metallic core.

12. The apparatus of claim 11, wherein said non-thrombogenic material is carbon.

13. The apparatus of claim 11, wherein said non-thrombogenic material is isotropic carbon.

14. A stent formed from a coil spring wire, said wire comprising:

an inner metallic core; and,

a first layer of plastic coating the inner metallic core; and

a second layer of non-thrombogenic material coating said first layer.

15. The apparatus of claim 14, wherein said plastic is polytetra fluorethylene (PTFE).

16. The apparatus of claim 15, wherein said non-thrombogenic material is carbon.

17. The apparatus of claim 15, wherein said non-thrombogenic material is isotropic carbon.

18. A medical procedure comprising the steps of:

positioning a coil spring stent in a spiral cavity of an insertion catheter, said insertion catheter comprising an outer sheathing cylinder and an inner core member, said spiral cavity formed by the cooperation of the inner lumen of said outer sheathing cylinder with a spiral groove formed in the inner core member;

advancing said insertion catheter to a preselected location in a vessel or duct of a living patient;

moving the distal end of the outer sheathing cylinder relative to the distal end of said inner core member, thereby allowing the coil spring stent to be released from the insertion catheter and to expand within the vessel or duct; and

removing the insertion catheter, allowing the coil spring stent to remain securely fixed within the vessel or duct.

19. The procedure of claim 18 further comprising the steps of:

advancing an angioplasty balloon to a position within the lumen of said expanded spring coil stent; and

expanding the angioplasty balloon to firmly imbed the spring coil stent into any stenotic plaque located along the vessel or duct wall; and

removing the angioplasty balloon.

20. The procedure of claim 18, wherein said advancing step included advancing said insertion catheter into a fallopian tube, for maintaining patency of the fallopian tube.

21. The procedure of claiml 8, wherein said advancing step included advancing said insertion catheter into a ureter, for maintaining patency of the ureter.

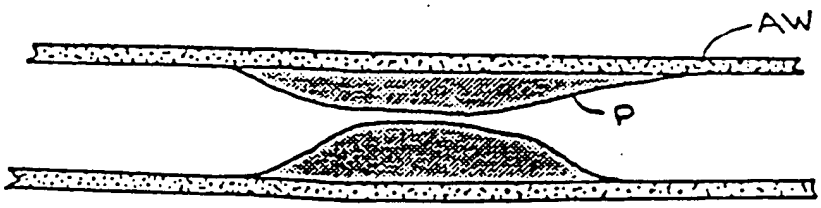

FIG. 1A

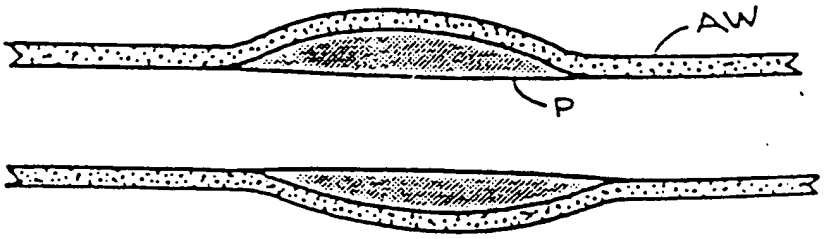

FIG. 1B

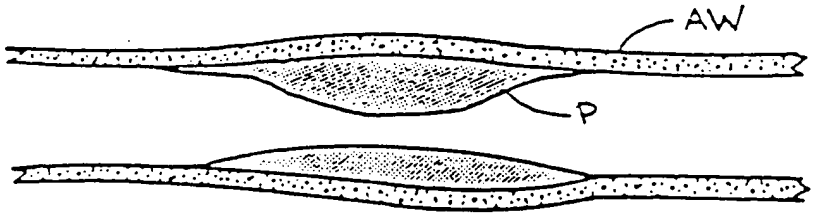

FIG. 1C

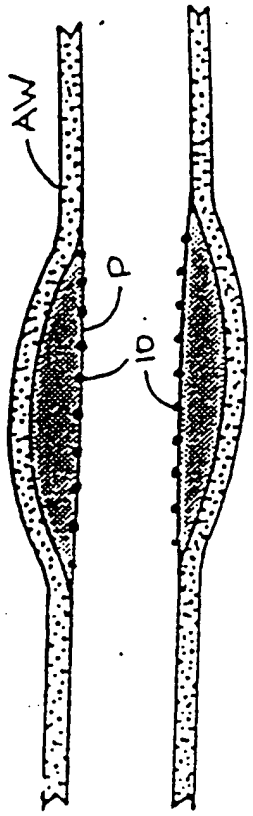

FIG. 2

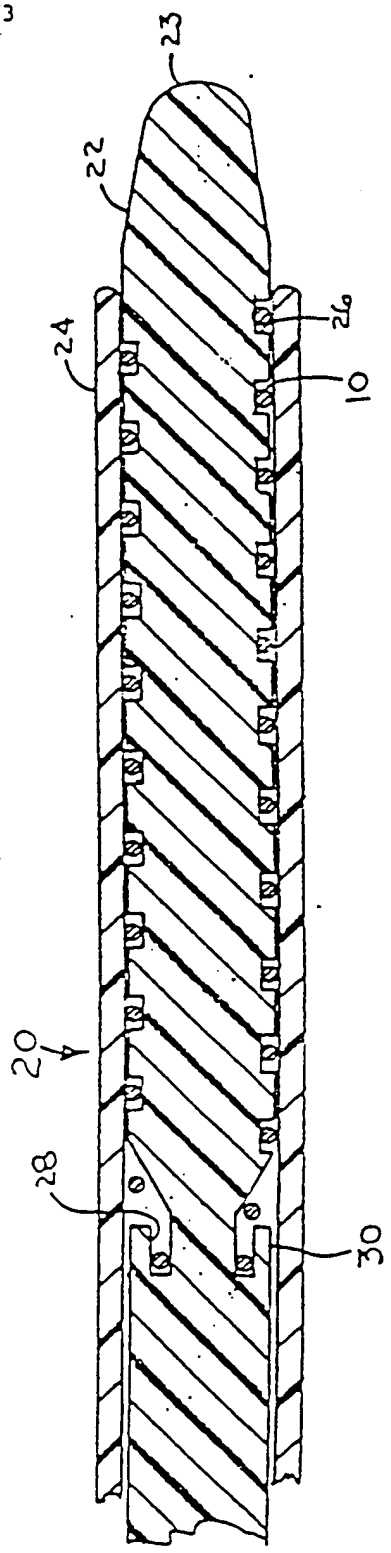

FIG. 3

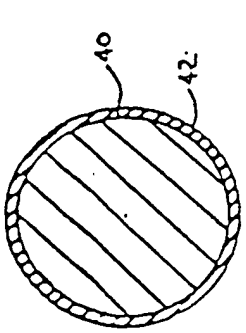

FIG. 5

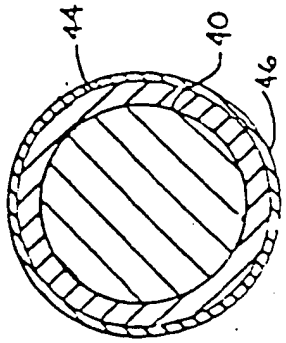

FIG. 6

FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No PCT/US87/00290

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (4): A61M 29/00

U.S. Cl. 128/341, 334R; 623/1

II. FIELDS SEARCHED

Minimum Documentation Searched

Classification System	Classification Symbols
U.S.	128/303R, 341, 343, 345, 334R, 348.1 623/1

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched

III. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
Y	US, A, 4,553,545 (MAASSET AL) 19 November 1985, see the entire document.	1-21
Y	US, A, 4,512,338 (BALKO ET AL) 23 April 1985, see the entire document.	1-21
Y, E	US, A, 4,655,771 (WALLSTEN) 07 April 1987 See the entire document.	1-21
Y, E	US, A, 4,649,922 (WIKTOR) 17 March 1987 See the entire document.	1-21
Y	US, A, 4,503,569 (DOTTER) 12 March 1985 See the entire document.	1-17
Y	US, A, 4,300,244 (BOKROS) 17 November 1981, see the entire document.	11-17
Y	US, A, 3,952,747 (KIMMELL) 27 April 1976 See column 5, lines 32-33.	11-17

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
22 April 1987	05 MAY 1987
International Searching Authority	Signature of Authorized Officer
ISA/US	M. Thaler

Form PCT/ISA/210 (second sheet) (May 1986)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

Y	"Expandable Intraluminal Graft: A Preliminary Study", Julio C. Palmaz et al, Radiology 1985; 156:73-77, see the entire document.	19

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers . because they relate to subject matter [2] not required to be searched by this Authority, namely:

2. ☐ Claim numbers . because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [3], specifically:

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [4]

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.